

# In The United States Patent and Trademark Office



In re Application of:

Assignee:

Genentech, Inc.

Inventors:

Phillip W. Berman et al.

Serial No.:

09/103,262

Filed:

June 23, 1998

For:

**METHODS AND** 

COMPOSITIONS FOR

VACCINATION AGAINST

HIV

Group Art Unit: 1648

Examiner:

Budens, R.

Attorney Docket No.: 14918-725 CON4

Certificate of Mailing Under 37 C.F.R. § 1.8

Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: May 26, 2000

Type or Print Name of Person Mailing: Gail Ohlsson

#### INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

# I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement:

Accompanies the new patent application submitted herewith. 37 CFR § 1.97(a).

[ ] Is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491.



[X] As far as is known to the undersigned, is filed before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 CFR §§ 1.17(p) or 1.17(i)(1).
[] Is filed after the first office action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 (Order No. 14918-725 CON4) for the fee (\$240) set forth in 37 CFR § 1.17(p) and any additional required fees.
[] Is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$130) set forth in 37 CFR § 1.17(i)(1) and a certification as specified in 37 CFR § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the information disclosure statement.
If either of the two immediately preceding paragraphs above referring to a certification are checked, the following "certification" under 37 CFR § 1.97(e) may need to be completed. The undersigned certifies that:
[] Each item of information contained in the information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
[] No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this information disclosure statement.
II. Copies of the Cited Items:
[] Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
[ ] Copies of only the following items listed on the attached Form PTO-1449 are enclosed:
[X] Copies of those items which are marked with an asterisk (*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Office in a prior Application No.08/226,162, filed April 11, 1994 (now Patent No. 5,674,984) and relied upon in this application for an earlier filing date under 35 U.S.C. § 120, which is a

divisional of 08/101,669 filed on August 2, 1993 (now abandoned), which is a continuation of 07/834,735 filed February 13, 1992 (now abandoned), which is a divisional of 07/504,785 filed April 3, 1990 (now abandoned). See 37 C.F.R. § 1.98(d).

[] Copies of those items which are marked with a double asterisk (\*\*) in the attached Form PTO-1449 are not supplied because they are U.S. patent application(s) and no copy of a U.S. patent application needs to be provided pursuant to 37 C.F.R. § 1.98(a)(2)(iii).

# III. Concise Explanation of Relevance:

[ ] A concise explanation of relevance of the items listed on Form PTO-1449 is not given.

[] A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references [copy attached].

[X] A concise explanation of relevance of the items listed on form PTO-1449 is given for only non-English language listed item(s). Specifically, the following foreign-language documents are being brought to the attention of the Examiner along with a concise explanation of the relevance of each document, as it is presently understood by the individual designated in 37 C.F.R. § 1.56(c) most knowledgeable about the content of the information in each document:

Reference B10 has been cited in the Japanese counterpart (App. No. 506683/1991) to the present application as relevant to Claims 19-21.

### IV. Conclusion:

Citation of the above documents shall not be construed as:

- 1. an admission that the documents are necessarily prior art with respect to the instant invention;
- 2. a representation that a search has been made, other than as described above; or
- 3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.



The Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any additional fees required in connection with the filing of this Information Disclosure Statement.

Please address all correspondence regarding this communication to the following address:

Emily M. Haliday McCutchen, Doyle, Brown & Enersen, LLP Three Embarcadero Center San Francisco, California 94111 Telephone: (650) 849-4910

Dated: May 26, 2000

Respectfully submitted,

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT	<del>11918 725 00111</del> 402E-918405 US	09/103,262
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#### REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	Subclass	Filing Date If Appropriate
	A1*	4,725,669	2/88	Essex et al:	530	322	
	A2*	<del>-5,166,050</del>	11/92	Shriver et al.	435	5	
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EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLAT'N	
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	B1*	<del>22320/89</del>	11/89	-Australia				
	B2*	65295/90	4/91	Australia				
	B3*	187041	9/86	Europe				
	B4*	<del>0 339 504 A2</del>	11/88	-Europe				

OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C1*	Allan et al., "Major glycopretein antigons that induce antibodies in AIDS patients are encoded by
	HTLV III" Science 228 (4703):1091-1094 (May 1985).
 C2*	Anderson-et-al., "Effect-of-Desc-and-Immunization-Schedule-on-Immune-Response-of-Baboons-to
	Recembinant Glycoprotein 130 of HIV-1," Jour-of Infectious Diseases, 160(6):960-969 (1989).
C3*	Arthur et al., "Ghallenge of Chimpanzees (Pan-troglodytes) Immunized with Human-Immunodeficionay
	Virus Envelope Glyseprotein gp120," Journ of Wirelegy 63(12):5046-5052 (1089).

### **EXAMINER**

## DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant(s).

· (Information Disclosure Statement — Section 9 PTO-1449 (Modified) [6-1])

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT	14918-725 CON4	09/103,262
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### REFERENCE DESIGNATION

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	B6*	<del>WO-89/12095</del>	12/89	PCT				
•	B7*	WO-90/02196	3/90	PCT				
	B8*	WO-91/13986	9/91	PCT				

OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C4*	Barin-ot al., "Virus-Envelope-Protein-of-HTL-V-III-Represents-Major-Target-Antigen-for-Antibodies-in
	AIDS Patients," Science 228:1094-1096 (1985).
C5*	Bewett-et-el., "Large-Scale-Broduction and Purification of a Maccinia Recombinant-Derived-HIV-1 gp160 and Analysis of Its-Immunogenicity," AIDS-Research and Human-Retroviruses 5(2):159-171 (1989).
C6*	Borman et al., "Expression and Immunogenicity of the Entracellular Domain of the Human- Immunodeficioney Virus Type I Envelope Glycoprotein, gp160" Jour of Virology 63(8):3489-3498 (1989).

**EXAMINER** 

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant(s).

(Information Disclosure Statement — Section 9 PTO-1449 (Modified) [6-1])

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	C7*	Barman et al. "Human imm	unodeficiency	vinus type 1 challenge of c	himpanze	es.immunize	d with	-
		recombinant envelope glyco	protein gp120	" Proc. Natl. Acad. Sci. US	4-85:520	) 5204 (1988 1 7 7 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	<del>-)</del> .	
	C8*	Berman et al., "Protection fr Cloned Type 1 Glycoprotein		erpes Simplex Virus Type ( 227:1400 1492 (1985)	2-Infection	-by-Vaccina	ion wi	<b>30</b>
	C9*	Berman et al., "Protection of Recombinant Glycoprotein-	Chimpanzee	s-From Infection by HIV-1			h	
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	C10*	Celltech "CHO cell rgp120" (	Certificate of	f Analysis pp.1-2 (Jan., 1990	).	177	17: ?	,
	C11*	Chakrabarti et.al., "Expression Nature 320:535-540 (1986).						
	C12*	Clements et al., "The V3 Loop Cleavage Sites; A Possible Fu (1991).	ns of the HI nction in V	V-1 and HIV-2 Surface Glyc iral Eusion" <i>AIDS Research</i>	coproteir and Hun	s Contain Pro nan Retroviru	teolyti ses 7:3.	: 16
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(Information Disclosure Statement — Section 9 PTO-1449 (Modified) [6-1])

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C13*	Desrosiers et al., "Vaccine pro				ection," Pr	oo-Natl.	
	Acad Sci_USA 86:6353_6357	(1989).					
C14*	Eabey et al., "Status of immur	e-based the	rapies in HIV infection and	AIDS," <i>Cli</i>	n_exp_Imr	<u>unol. 88</u> :1-	
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### OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

	C16*	Fox, LL, "No Winners Against AIDS," Bio/Technology 12:128 (Feb. 1994).
	C17*	Homsy et al., "The Ec and Not CD4 Receptor Mediates-Antibody-Enhancement of LIIV Infection in
•		Human-Golls," Soience 244:1357-1360 (1989):
	C18*	Huetal, "Effect of Immunization With a Vaccinia HIV on Recombinant on HIV Infection of
		Chimpanzess," Nature 328:721-723 (1987).

EXAMINER DATE CONSIDERED

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(Information Disclosure Statement - Section 9 PTO-1449 (Modified) [6-1])

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C19*	Hu et al., "Expression of AIDS virus envelope gene in recombinant vaccinia viruses," Nature 320:537-
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C20*	Jahanerian et al. "Principal neutralizing domain of the human immunodeficioney virus type 1 envelope
	protein," Proc. Natl. Acad. Sci. USA 86:6768-6772 (1989).
 C21*	Kitchen et al. "Actiology of AIDS - antibodies to human T cell leukacmia virus (type III) in
	haemonhiliacs." Nature 312:367-369 (1984)

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### OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

<del></del>	C25*	Lasky et al., "Neutralization of the AIDS Retrovirus by Antibodies to a Recombinant Envelope
		Glycoprotoin," Science 233:209-212 (1986).
	C26*	Letvin et al., "AIDS like Disease in Macaque Monkeys Induced By Simian Immunodeficiency Virus: A Vaccine Trial," Vaccines 87:209-213 (1987).
	C27	Liou, Ruey-Shyan et al., "A Chimeric Mouse-Human Antibody That Retains Specificity For HIV gp120 And Mediates The Lysis of HIV-Infected Cells," Journal of Immunology 143:3967-3975 (Dec. 1989).

EXAMINER DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant(s).

(Information Disclosure Statement — Section 9 PTO-1449 (Modified) [6-1])

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT	14918-725 CON4	09/103,262
(Use several sheets if necessary)	APPLICANT Phillip W. Berman et al.	
	FILING DATE June 23, 1998	GROUP ART UNIT 1643

## REFERENCE DESIGNATION U.S. PATENT DOCUMENTS

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	B39				<u> </u>			
	B40				<u> </u>		<u> </u>	

OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C	C28*	Leoney et al., "Type Restricted Neutralization of Molecular Clones of Human Immunodeficiency
		Virus," Science 241-357-359 (1988)
C	229*	Matsushita et al., "Characterization of a Human Immunodeficiency Virus Neutralizing Monoclonal Antibody and Mapping of the Neutralizing Epitope," Jour. of Vivology 62(6):2107-2114 (1988).
C	C30*	Medrow et al. "Computer-Assisted Analysis of Envelope Protein Sequences of Seven Human Irangunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," Journ of Vivology 61(2):570-578 (1987).

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	C32*	Nowmark, Potor, "Recoding L	lopes of AH	OS vaccines," Nature 333:69	9 (1988).				
	C33*	Palker et al., "Type specific n	outralization	of the human immunodefic	ioncy virus	with antib	odies t	0	
		env-encoded synthetic peptide	s," <i>Proc.</i> N	atl. Acad. Sci. USA-85+1932	1936 (1988	<del>9).</del>			
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FORM	PTO-144	9 (Modified)		ATTY. DOCKET NO.	SER	IAL NO.		
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	C35*	Roboy et al, "Prospect for pre	vention of h	ıman immunodeficiency vi	rus infectio	n: Purified	120_kDa	
<del></del>	C26*	envelope glycoprotein induces Robey, W.G. et al., "Character	neutralizing	antibody," Hros. Natl. Aca	a SCL SS:	te of HTI	UNAD).	
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	C37*	Rebinson, Jr. et al., "Antibody Infection," The Lancet 790-79		Enhancement of Human in	<del>ининовоне</del>	<del>ichoy viru</del>	<del>y rypu</del> 1	
	C38*	Robinson, Jr. et al., "Human A	Appoclanal	Antibodies to the Human Im	munodofic	iency Viru	S-Type 1	
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		USA-87:3185-3189 (1990):	_					
	C39*	Rusche et al., "Antibodies The	t Inhibit Fu	sion of Human Immunodefi	ciency Viru	s-infected	Cells Bind a	
		24-amino-Acid Sequence of the	ie-Viral-Env	elope <del>, gp120;"-<i>Proo-Nath-A</i></del>	<del>load-Soi-L</del>	<del>(3.4-83:311)</del>	<del>కావడ</del> 02	
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	C40*	Salk et al., "Centrel of Influent (1977).				Science 19	5.834_8	47		
	C41*	Salk, Jonas, "Prospects for the 927:473-476 (1987).		·	ositive-Ind	ividuals," À	latura.	,		
	C42*	Stephens et al., "A-chink-in-H	<del>V's armour</del>	? <u>" Nature 343;219 (1990</u> ).						
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	C44*	Vandenbark et al., "Immuniza Experimental Autoimmune Er	tion with a	Synthetic T cell Receptor V	region Pop	tide Protec	ts Against	
	C45*	Van Eendenburg et al., "Cell- Vaccinated With Different Va 50 (1989).	Mediated-In	mune-Proliferative-Respon	ses to HIV	l of Chimp n Retroviri	<del>anzess=</del> (ses 5(1):41-	
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	C47	Yoshida, Nobuko et al., "Meta			al Antibody	/ 10D8 Dir	ected to	the	
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	C48*	Zagury-et-al., "Immunization-	Against-AIE	S-in-Humans <del>," Nature 326:</del>	249-250 (19	287).			
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